

# False claims must be abandoned urgently

It is understandable that a company should want its products to be as attractive and enticing to the consumer as possible, but it would seem that there are some manufacturers who are prepared to take their chances and go over the strict barriers and guidelines that are clearly defined by law. There is also a trend to tell us what a particular formula does not contain and by so doing imply that the product is safer, but nothing could be further from the truth.

## Definitions

The EEC Council Directive 76/768/EEC, up to the 27<sup>th</sup> amending Directive 2003/15/EC and including the previous 26 amendments, has to be translated into the language of each member state. In the UK the law is Statutory Instrument 2004 No. 2152 The Cosmetic Products (Safety) Regulations 2004 (107 pages).

In addition, products must not infringe the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994, a very common infringement with today's eagerness to have alluring marketing copy on the packaging. The regulations state that, unless exempt, any "medicinal product" to which Chapters II to V of Directive 2001/83/EEC apply must not be placed on the UK market unless it has a marketing authorisation (product licence) granted by the European Commission or by the UK Licensing Authority. The Act similarly states that, unless exempt, any other "medicinal product" must not be sold or supplied without a marketing authority. A marketing authorisation or product licence is only granted for a product that meets statutory standards of safety, quality and efficacy.

The status of many products on the borderline between medicinal products and food supplements, and cosmetic or medical devices can be difficult to determine. The MHRA, or Medicines and Healthcare products Regulatory Agency (formerly the MCA or Medicines Control Agency), has produced a Guidance Note 8 document to explain how and on what basis the MCA decides whether products



*Consumers will identify dishonesty and meaningless statements.*

are medicines or not. It includes guidance on the statutory procedures in Regulation 3A of the Regulations introduced by the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2000 (S.I. 2000/292).

There is also the requirement to ensure that claims made on the packaging comply with the Trade Descriptions Act 1968, Control of Misleading Advertising Regulations 1988 (as amended). Products must also comply with the Weights and Measures Act 1985. Certain categories (e.g. insect repellents and products that contain this property) may also be subject to the Statutory Instrument 2003 No. 429 The Biocidal Products (Amendment) Regulations 2003.

Compliance with these laws is mandatory in Europe and many countries have adopted them with little alteration. It will be the way of things to come and most countries are in the process of harmonising and adopting these legal safeguards. Any company that does not react ahead of the inevitable is going to find it an arduous and almost impossible task to implement in the time frames that are normally allowed for full compliance.

## The MHRA

### What is a medicinal product?

The MHRA has issued a booklet that may be obtained freely from its internet site ([www.mhra.gov.uk](http://www.mhra.gov.uk)). It is called Guidance Note 8 and this document is used as a basis for discussion. The following paragraph is taken from this publication:

"The Cosmetics Directive 76/768/EEC as amended (implemented in the UK by the Cosmetic Products [Safety] Regulations 2004 [SI 2004/2152] as amended), harmonises the requirements for cosmetics in the European Community to achieve free trade in cosmetics whilst ensuring that the products are safe and consumers are not misled. It prohibits, or places restrictions on, certain ingredients and defines a cosmetic product. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in Directive 2001/83/EEC. If a product falls within the definition of a cosmetic

and within the definition of a medicinal product it will be classified as a medicinal product (Delattre 1991, C-369/88). The regulatory status of products in other Member States will also be taken into account."

Article 1 of Directive 2001/83/EEC as amended, defines a medicinal product as:

"(a) Any substance or combination of substances presented as *having properties for treating or preventing disease in human beings* ['the first limb'];

(b) Any substance or combination of substances which may be *used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis* ['the second limb']."

- (Note: The paragraph identifications (a) and (b) are not part of the definition and are added here solely for ease of reference later on. Changes to the definition which came into effect from 30 October 2005 are shown in italics to aid identification.)

Medicinal products may well fall under both limbs of the definition but the European Court of Justice (ECJ) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product: "Directive 65/65 (now Directive 2001/83) provides two definitions of the term "medicinal product"; one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions." (Upjohn 1989, C-112/89).

It is the infringement of these regulations that causes problems for the consumer and the Borderline Substances division of the MHRA. The proliferation of products that clearly intend to mislead the consumer into believing that a product will exert a physiological effect is on the increase. There are elements within the industry that are determined to jeopardise a sane consumer's credibility with product suggestions that are so ludicrous as to be lamentable.

### The Cosmetic Products (Safety) Regulations 2004

Let us refresh our memories with the exact wording of the law in relation to the definition of a cosmetic, toiletry or skin care product. Cosmetic product means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (i.e. the epidermis, hair system, nails, lips

and external genital organs) or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours, except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.

"Cosmetic product intended to come into contact with the mucous membranes" means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin.

There is no degree of freedom and there is no possible scope for interpretation – the law is precise and specific. You may only protect the body with your product. It might be suitable for those with eczema-prone skin and it may be helpful for those liable to get spots and pimples, but it is never allowed to be a treatment for medicinal conditions, because that would be achieved using drugs or medicines.

Once again this is a huge stumbling block and the MHRA says:

"Again in context, and particularly in the case of products on the borderline between food and medicinal products, claims to 'protect' or 'avoid' may be perceived by consumers as having much the same meaning as 'prevent'. For example, a product may be presented to 'protect' a consumer against a specific disease or adverse condition in such a way that consumers would believe that the product could 'prevent' it".

You may see words like "kills the bacteria responsible for producing spots" or "moisturises the skin to stop it from becoming dry and itchy (pruritic)." Any product that uses the word "heal" or states that a product will be a remedy or treatment for any disease is breaking the law. The MHRA says: "Claims to relieve symptoms, or to cure, remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims."

The beauty industry targets the population in areas of stress, obesity, lifestyle and being healthy. Beauty requires a good diet, plenty of exercise, low alcohol consumption, a no smoking policy and plenty of sleep. All of these things in combination would give all of us a good start to the looking good, feeling good trail. Sadly, one should also stay out of

the sun altogether – even safe tanning will age the skin faster than is the case with those who dwell in the shade under trees or umbrellas.

The MHRA does not consider claims to "maintain" or "help to maintain" or "support" health or a healthy lifestyle as medicinal in themselves. Nor, if such claims are made in relation to healthy bodily functions or organs is the MHRA likely to consider them as presenting the product for treating or preventing disease. In general, the MHRA is only likely to consider "health maintenance" claims as medicinal if they suggest or imply that a product, perhaps targeted at a vulnerable section of the population, may restore, or help to restore, a specific bodily function or organ to a normal healthy state.

The balance of common sense seems to be thrown over by unbelievable promises using magical products that will reduce weight in a single application. There are even products that claim to suck toxins out through the skin by strapping giant Japanese tea bags full of saw dust and other herbal detritus on to the soles of the feet.

To follow are examples of unrealistic claims:

"The body wrap is an advanced development that works on shrinking the adipose tissue of fat called cellulite that is found directly below the surface of the skin. Body wrapping eliminates toxins and impurities that have built up in the body and helps to rid the body of cellulite. It detoxifies your body, tightens loose tissue, exfoliates, smoothes and softens your skin."

"Lose 5 to 15 inches in one Body Wrap! Schedule three or more wraps for better results within 7-10 days of each other. Reduce the appearance of cellulite and stretch marks."

"The System is an all-natural detox and inch loss program, which draws out toxins and tightens the skin. The bandages are soaked in a solution and applied warm, allowing the solution to open pores and draw out toxic accumulations from the lymph system which can be caused by stress, metabolic waste, medication and pollution. Proven wrapping techniques tighten the skin, compact tissue and firm-up the body quickly."

"Will the lost inches return? Clients have kept off the inches as long as they maintain their weight. Are there any medical considerations? If you are on medication or have any physical conditions you should obtain your doctor's permission. How long does it take? The entire process takes approximately 3 hours."

Toxins are removed from the body by the liver and kidneys with some contribution being afforded by the exhalation of gases through the lungs and expectoration of damaging phlegm that may have accumulated in the lungs by the act of coughing. Lymph nodes act as filters, with an internal honeycomb of reticular connective tissue filled with lymphocytes that collect and destroy bacteria and viruses. When the body is fighting an infection, lymphocytes multiply rapidly and produce a characteristic swelling of the lymph nodes. The idea that a bandage soaked in colloidal clay can remove toxins is non-factual and could be dangerous to anyone who believes that it could sort out a truly dangerous medical problem in which toxins are involved. Furthermore, weight is measured in pounds and ounces or grams and kilograms, not in inches, and the idea that one can lose weight by wrapping the body in a few bandages for an hour or so is ridiculous. It is hard to believe that the Trading Standards Office has not prosecuted already. Maybe it will when presented with the evidence (or lack of it).

### What's not included

Scientists go to huge lengths to include wonderful things in their products but the trend now seems to be to tell the consumer what is not in there, and most of the time the thing left out is safer than what has been put in as a replacement.

Natural ingredients are often held up as being a lot safer than their synthetic counterparts and although nature is a wonderful provider it is wrong to make any assumptions on the benign status of natural products. Indeed many chemotherapy drugs are derived from plant sources like taxol, vincristine, vinblastine and podophyllotoxin. A good number of deadly poisons such as strychnine, colchicines, nicotine and rotenone are plant based. See drug list (Table 1).

### Contains no parabens

The first exclamation has to be "Why not?". Parabens are found in nature – they are extremely safe and occur in the food we eat. Could it be that poor science supplied in the name of breast cancer is to blame?

In the plant world, 4-hydroxybenzoic acid and its derivatives are commonly found in various vegetable foods such as barley, strawberries, blackcurrants, peaches, carrots, onions, cocoa-beans and vanilla. It is also found in foods prepared from fruit plants, and in fruit juices, yeast extract, wine vinegar and cheeses. A total of 122 plant species have been investigated and the acid

**Table 1: Part 1**

Drug/chemical	Action/clinical use	Plant source
(+)-Catechin	Haemostatic	<i>Potentilla fragarioides</i>
Acetyldigoxin	Cardiotonic	<i>Digitalis lanata</i>
Adoniside	Cardiotonic	<i>Adonis vernalis</i>
Aescin	Anti-inflammatory	<i>Aesculus hippocastanum</i>
Aesculetin	Anti-dysentery	<i>Frazinus rhychophylla</i>
Agrimophol	Anthelmintic	<i>Agrimonia supatoria</i>
Ajmalicine	Circulatory disorders	<i>Rauwolfia sepentina</i>
Allantoin	Vulnerary	Several plants
Allyl isothiocyanate	Rubefacient	<i>Brassica nigra</i>
a-Lobeline	"Smoking deterrent, respiratory stimulant"	<i>Lobelia inflata</i>
Anabesine	Skeletal muscle relaxant	<i>Anabasis sphylla</i>
Andrographolide	Bacillary dysentery	<i>Andrographis paniculata</i>
Anisodamine	Anticholinergic	<i>Anisodus tanguticus</i>
Anisodine	Anticholinergic	<i>Anisodus tanguticus</i>
Arecoline	Anthelmintic	<i>Areca catechu</i>
Asiaticoside	Vulnerary	<i>Centella asiatica</i>
a-Tetrahydrocannabinol (THC)	"Anti-emetic, decrease ocular tension"	<i>Cannabis sativa</i>
Atropine	Anticholinergic	<i>Atropa belladonna</i>
Benzyl benzoate	Scabicide	Several plants
Berberine	Bacillary dysentery	<i>Berberis vulgaris</i>
Bergenin	Antitussive	<i>Ardisia japonica</i>
Betulinic acid	Anticancerous	<i>Betula alba</i>
Borneol	"Antipyretic, analgesic, anti-inflammatory"	Several plants
Bromelain	"Anti-inflammatory, proteolytic"	<i>Ananas comosus</i>
Caffeine	CNS stimulant	<i>Camellia sinensis</i>
Camphor	Rubefacient	<i>Cinnamomum camphora</i>
Camptothecin	Anticancerous	<i>Camptotheca acuminata</i>
Chymopapain	"Proteolytic, mucolytic"	<i>Carica papaya</i>
Cissampeline	Skeletal muscle relaxant	<i>Cissampelos pareira</i>
Cocaine	Local anaesthetic	<i>Erythroxylum coca</i>
Codeine	"Analgesic, antitussive"	<i>Papaver somniferum</i>
Colchicine amide	Antitumor agent	<i>Colchicum autumnale</i>
Colchicine	"Antitumor agent, anti-gout"	<i>Colchicum autumnale</i>
Convallatoxin	Cardiotonic	<i>Convallaria majalis</i>
Curcumin	Choleretic	<i>Curcuma longa</i>
Cynarin	Choleretic	<i>Cynara scolymus</i>
Danthron	Laxative	<i>Cassia species</i>
Demecolcine	Antitumor agent	<i>Colchicum autumnale</i>
Deserpidine	"Antihypertensive, tranquilliser"	<i>Rauwolfia canescens</i>
Deslanoside	Cardiotonic	<i>Digitalis lanata</i>
Digitalin	Cardiotonic	<i>Digitalis purpurea</i>
Digitoxin	Cardiotonic	<i>Digitalis purpurea</i>
Digoxin	Cardiotonic	<i>Digitalis purpurea</i>
Emetine	"Amoebicide, emetic"	<i>Cephaelis ipecacuanha</i>
Ephedrine	"Sympathomimetic, antihistamine"	<i>Ephedra sinica</i>
Etoposide	Antitumor agent	<i>Podophyllum peltatum</i>
Galanthamine	Cholinesterase inhibitor	<i>Lycoris squamigera</i>
Gitalin	Cardiotonic	<i>Digitalis purpurea</i>
Glasiovine	Antidepressant	<i>Octea glaziovii</i>
Glaucarubin	Amoebicide	<i>Simarouba glauca</i>
Glaucine	Antitussive	<i>Glaucium flavum</i>
Glycyrrhizin	"Sweetener, Addison's disease"	<i>Glycyrrhiza glabra</i>
Gossypol	Male contraceptive	<i>Gossypium species</i>
Hemsleyadin	Bacillary dysentery	<i>Hemsleya amabilis</i>
Hesperidin	Capillary fragility	Citrus species
Hydrastine	"Hemostatic, astringent"	<i>Hydrastis canadensis</i>
Hyoscyamine	Anticholinergic	<i>Hyoscyamus niger</i>
Irinotecan	"Anticancer, antitumor agent"	<i>Camptotheca acuminata</i>
Kaibic acid	Ascaricide	<i>Digenea simplex</i>
Kawain	Tranquilliser	<i>Piper methysticum</i>
Kheltin	Bronchodilator	<i>Ammi visaga</i>

was found present in all of them. 4-hydroxybenzoic acid is the most widely distributed aromatic organic acid in the vegetable kingdom. The Scandinavian cloudberry contains benzoic acid, sorbic acid, salicylic acid and 2-hydroxybenzoic acid, as well as methyl and propyl parabens, which all account for the superior resistance of cloudberry to microbial spoilage.

Liz Earle, a well-informed brand, states: "Parabens occur naturally in many fruits and are used as preservatives in some of our products, but only in very small quantities."

### In Australia

NICNAS (National Industrial Chemicals Notification and Assessment Scheme – [www.nicnas.gov.au](http://www.nicnas.gov.au)) is an independent and highly thorough organisation. It has reviewed publications and other available data on the health effects of parabens. The study by Darbre *et al* (2004) utilised a small sample (20), and analysed the breast tissue (or other tissues from affected women) for the source(s) of the parabens found in the breast tumours. Routes of exposure were not identified. This paper, however, notes the need for further research to establish the significance of the presence of parabens in these tumours and to establish any link between parabens in underarm cosmetics and the development of breast cancer.

Data from published sources indicates that parabens demonstrate weak oestrogenic activity in some experimental animals and that enzymes present in skin cells and subcutaneous fat cells are capable of breaking down topically applied parabens.

Following analysis of all available data, NICNAS believes that further research is required before a causal link between parabens in cosmetic products and breast cancer can be established. Parabens in cosmetic products are considered safe to use when the products are used as directed.

### In Europe

The Scientific Committee on Consumer Products (SCCP) reporting on "Parabens, underarm cosmetics and breast cancer" in January 2005, looked at a series of questions, including: Do the data provided indicate a potential risk for the development of breast cancer in past users of underarm cosmetics?

There are insufficient data to establish a clear link between the use of underarm cosmetics and breast cancer. The authors of the studies that led to the suggestion of a connection clearly state that they did not have the intention to prove such a

Table 1: Part 2

Drug/chemical	Action/clinical use	Plant source
"Lanatosides A, B, C"	Cardiotonic	<i>Digitalis lanata</i>
Lapachol	"Anticancer, antitumor"	<i>Tabebuia</i> sp
L-Dopa	Anti-Parkinsonism	<i>Mucuna</i> sp
Menthol	Rubefacient	<i>Mentha</i> species
Methyl salicylate	Rubefacient	<i>Gaultheria procumbens</i>
Monocrotaline	Antitumor agent (topical)	<i>Crotalaria sessiliflora</i>
Morphine	Analgesic	<i>Papaver somniferum</i>
Neoandrographolide	Dysentery	<i>Andrographis paniculata</i>
Nicotine	Insecticide	<i>Nicotiana tabacum</i>
Nordihydroguaiaretic acid	Antioxidant	<i>Larrea divaricata</i>
Noscapine	Antitussive	<i>Papaver somniferum</i>
Ouabain	Cardiotonic	<i>Strophanthus gratus</i>
Pachycarpine	Oxytocic	<i>Sophora psychocarpa</i>
Palmatine	"Antipyretic, detoxicant"	<i>Coptis japonica</i>
Papain	"Proteolytic, mucolytic"	<i>Carica papaya</i>
Papavarine	Smooth muscle relaxant	<i>Papaver somniferum</i>
Phylodulcin	Sweetner	<i>Hydrangea macrophylla</i>
Physostigmine	Cholinesterase inhibitor	<i>Physostigma venenosum</i>
Picrotoxin	Analeptic	<i>Anamirta cocculus</i>
Pilocarpine	Parasympathomimetic	<i>Pilocarpus jaborandi</i>
Pinitol	Expectorant	Several plants
Podophyllotoxin	Antitumor anticancer agent	<i>Podophyllum peltatum</i>
"Protoveratrine A, B"	Antihypertensives	<i>Veratrum album</i>
"Pseudoephedrine, nor-"	Sympathomimetic	<i>Ephedra sinica</i>
Pseudoephedrine	Sympathomimetic	<i>Ephedra sinica</i>
Quinidine	Antiarrhythmic	<i>Cinchona ledgeriana</i>
Quinine	"Antimalarial, antipyretic"	<i>Cinchona ledgeriana</i>
Quisqualic acid	Anthelmintic	<i>Quisqualis indica</i>
Rescinnamine	"Antihypertensive, tranquilliser"	<i>Rauvolfia serpentina</i>
Reserpine	"Antihypertensive, tranquilliser"	<i>Rauvolfia serpentina</i>
Rhomitoxin	"Antihypertensive, tranquilliser"	<i>Rhododendron molle</i>
Rorifone	Antitussive	<i>Rorippa indica</i>
Rotenone	"Piscicide, insecticide"	<i>Lonchocarpus nicou</i>
Rotundine	"Analgesic, sedative, tranquilliser"	<i>Stephania sinica</i>
Rutin	Capillary fragility	Citrus species
Salicin	Analgesic	<i>Salix alba</i>
Sanguinarine	Dental plaque inhibitor	<i>Sanguinaria canadensis</i>
Santonin	Ascaricide	<i>Artemisia maritima</i>
Scillarin A	Cardiotonic	<i>Urginea maritima</i>
Scopolamine	Sedative	<i>Datura</i> species
"Sennosides A, B"	Laxative	<i>Cassia</i> species
Silymarin	Antihepatotoxic	<i>Silybum marianum</i>
Sparteine	Oxytocic	<i>Cytisus scoparius</i>
Stevioside	Sweetner	<i>Stevia rebaudiana</i>
Strychnine	CNS stimulant	<i>Strychnos nux-vomica</i>
Taxol	Antitumor agent	<i>Taxus brevifolia</i>
Teniposide	Antitumor agent	<i>Podophyllum peltatum</i>
Tetrahydropalmatine	"Analgesic, sedative, tranquilliser"	<i>Corydalis ambigua</i>
Tetrandrine	Antihypertensive	<i>Stephania tetrandra</i>
Theobromine	"Diuretic, vasodilator"	<i>Theobroma cacao</i>
Theophylline	"Diuretic, bronchodilator"	<i>Theobroma cacao</i> and others
Thymol	Antifungal (topical)	<i>Thymus vulgaris</i>
Topotecan	"Antitumor, anticancer agent"	<i>Camptotheca acuminata</i>
Trichosanthin	Abortifacient	<i>Trichosanthes kirilowii</i>
Tubocurarine	Skeletal muscle relaxant	<i>Chondodendron tomentosum</i>
Valaprotiatries	Sedative	<i>Valeriana officinalis</i>
Vasicine	Cerebral stimulant	<i>Vinca minor</i>
Vinblastine	"Antitumor, antileukemic agent"	<i>Catharanthus roseus</i>
Vincristine	"Antitumor, antileukemic agent"	<i>Catharanthus roseus</i>
Yohimbine	Aphrodisiac	<i>Pausinystalia yohimbe</i>
Yuanhuacine	Abortifacient	<i>Daphne genkwa</i>
Yuanhuadine	Abortifacient	<i>Daphne genkwa</i>

link. Two recent epidemiological studies on the use of underarm cosmetics in relation to breast cancer exist: Mirick *et al* 2002 and McGrath 2003. The authors of these studies could not establish a relationship. Moreover, according to current knowledge in this field, age is the major risk factor with regard to the incidence of breast tumours, followed by family history of breast cancer (De Grève 2004).

The effect of hormones has been acknowledged, but not all cancers are oestrogen receptor positive. In fact, it is strongly suggested that for the pathogenesis of a significant proportion of all breast cancers, hormones do not play a significant role. It is true, however, that oestrogens might have a role through their mitogenic action to further stimulate the malignant transformation of premalignant cells (De Grève 2004).

For this reason, exposure to potent oestrogens should be avoided whenever possible.

Further important clinical data are:

- Breast cancer tumours occur most frequently in the upper quadrant of the breast (closest to the armpit). A clear relationship, however, has been found with the amount of gland tissue present at that location.
- It is clinically well-established that the circulation of blood/lymph goes from the breast towards the armpit and further towards different organs and tissues and not vice versa, making an exchange process from the armpit towards the breast tissue highly speculative.

It is the opinion of the SCCP that, viewing the current knowledge, there is no evidence of demonstrable risk for the development of breast cancer caused by the use of underarm cosmetics.

In particular, do the data provided indicate a potential risk for the development of breast cancer in past users of underarm cosmetics containing parabens?

With regard to their general toxicological profile, acute, subacute and chronic toxicity, studies in rats, dogs and mice have proven parabens to be practically non-toxic, not carcinogenic, not genotoxic or co-carcinogenic, and not teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolysed (SCF 1994).

In a number of *in vitro* studies, such as the recombinant yeast oestrogen screen, parabens have proven to be able to bind to the oestrogen receptor, to activate genes controlled by these receptors,

**Table 2: Ingredients**

1	Amyl Cinnamyl Alcohol (Amyl Cinnamic Alcohol)
2	Amyl Cinnamal
3	Anisyl Alcohol (Anise Alcohol)
4	Benzyl Alcohol
5	Benzyl Benzoate
6	Benzyl Cinnamate
7	Benzyl Salicylate
8	Cinnamyl Alcohol
9	Cinnamal
10	Citral
11	Citronellol
12	Coumarin
13	Eugenol
14	Farnesol
15	Geraniol
16	Hexyl Cinnamaldehyde (Hexyl Cinnamal) CTFA
17	Hydroxycitronellal
18	Isoeugenol
19	2-(4-tert-Butylbenzyl) Propionaldehyde (Lilial) Butylphenyl methylpropional (CTFA)
20	Limonene
21	Linalool
22	Hydroxymethylpentylcyclohexene-carboxaldehyde (Lyral) Hydroxyisohexyl-3-cyclohexene carboxaldehyde (CTFA)
23	Methyl Heptin Carbonate
24	3-Methyl-4(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (Methyl Ionone) Alpha-isomethyl ionone (CTFA)
25	Oakmoss Extract
26	Treemoss Extract
	Not found in essential oils

and to stimulate cell growth and increase the level of immune reactive oestrogen receptor protein. The oestrogenic potency increases with increasing length and branching of the alkyl side chains (methyl < ethyl < propyl < butyl < isobutyl), but remains at all times 1,000 to 1,000,000 times below the potency of 17 $\beta$ -estradiol. Hydroxybenzoic acid, the common metabolite of all parabens, appears to be inactive in the *in vitro* assays. The *in vivo* oestrogenic activities of parabens have been tested in uterotrophic assays employing either immature female rodents or adult ovariectomised female rodents after oral, subcutaneous or dermal administration. Again, butyl paraben appeared being more potent than propyl, ethyl and methyl paraben, and again the values remained several magnitudes of order below the potency of 17 $\beta$ -estradiol. Conflicting results have been reported for p-hydroxybenzoic acid tested *in vivo*. One study claimed that it has no oestrogenic effect. Another study gives potency values 1,000-fold below the 17 $\beta$ -estradiol level (EFSA 2004, Anonymous 2004, Paulsen and Alexander 2003).

In view of the fact that the oestrogenic

potential of parabens has been found to be very low, it is the opinion of the SCCP that, in the light of the present knowledge, there is no evidence of demonstrable risk for the development of breast cancer caused by the use of paraben-containing underarm cosmetics.

#### In the UK

The most relevant body is the CTPA (Cosmetic, Toiletry and Perfumery Association – [www.ctpa.org.uk](http://www.ctpa.org.uk)). There are many quotes to be found relating to the latest reports on parabens and breast cancer, including the following expert comment:

“The findings of parabens in tumour samples are additional results in line with the general hypothesis that there may be a link between oestrogenic compounds commonly used in underarm cosmetics and other consumer products and breast cancer. The results alone, however, do not suggest that these chemicals caused the tumours in these patients. Darbre *et al*’s findings invite several questions: how did the parabens get into the breast, are they persistent and could

they do harm? The answers require further research.”

In their general considerations and conclusion from the editorial of the *Journal of Applied Toxicology* in which research was published, Philip W. Harvey and David J. Everett comment: “We are all exposed to all kinds of chemicals but it doesn’t mean that they all cause cancer. The question here is whether the chemicals would have an impact on the hormones, and also what level you would see in a healthy breast tissue. A causal link has by no means been proved.”

Karol Sikora, professor of oncology at Imperial College London, writing in *The Observer* newspaper (11 January 2004), states: “No causal link has been found between underarm cosmetics containing parabens and breast cancer. There is also no robust population-based evidence to suggest a link. Should any notional risk exist it would be insignificant when compared to other avoidable environmental risks for the disease, such as obesity.”

Dr Richard Sullivan, head of clinical programmes at Cancer Research UK, was quoted in the following newspapers: *The Sun*, *The Star*, *Daily Mail*, *The Independent* and *The Observer* (12 January 2004): “This extremely small study does not demonstrate a direct or causal link between deodorant or anti-perspirant use and developing breast cancer. Further research is needed to establish the source of the chemicals found in the breast tumour samples and what, if any, the relationship is to breast cancer.”

Delyth Morgan of Breakthrough Breast Cancer was also quoted in the *Daily Mail* and *Daily Mirror* (12 January 2004): “We conclude from our results that the above mentioned paraben esterase III of keratinocytes (a skin enzyme that breaks down parabens) is sufficient to completely hydrolyse the traces of parabens that may enter the skin from topically applied ointments.”

Further comment can be found in: Hydrolysis of parabens by extracts from differing layers of human skin; C. Lobermeier, C. Tschoetschel, S. Westie and E. Heymann. *Biol.Chem.* 377(1): 647-651 (1996).

Even Breakthrough, the breast cancer awareness organisation, decries the risks ([www.breakthrough.org.uk](http://www.breakthrough.org.uk))

#### In the USA

The FDA (Food and Drug Administration – [www.cfsan.fda.gov](http://www.cfsan.fda.gov)) is the governing body. The following response to the question of what health risks are associated with the

#### Cosmetic Ingredient Review

The Cosmetic Ingredient Review (CIR) was established in 1976 by CTFA. CIR endeavours to assess the safety of ingredients used in cosmetics in an unbiased, expert manner. Its findings have established a public record of the safety of cosmetic ingredients. The heart of the CIR programme is the independent expert panel that consists of world-renowned physicians and scientists. Expert panel members must be free of any conflicts of interest, and must meet the same conflict of interest requirements as outside experts to the Food and Drug Administration (FDA).

use of parabens in cosmetics was given: “The Cosmetic Ingredient Review (CIR) reviewed the safety of methylparaben, propylparaben, and butylparaben in 1984 and concluded they were safe for use in cosmetic products at levels up to 25%. Typically parabens are used at levels ranging from 0.01 to 0.3%.”

On 14 November 2003, the CIR began the process to reopen the safety assessments of methylparaben, ethylparaben, propylparaben, and butylparaben in order to offer interested parties an opportunity to submit new data for consideration. In September 2005, the CIR decided to reopen the safety assessment for parabens to request exposure estimates and a risk assessment for cosmetic uses. In December 2005, after considering the margins of safety for exposure to women and infants, the panel determined that there was no need to change its original conclusion that parabens are safe as used in cosmetics. (The CIR is an industry-sponsored organisation that reviews cosmetic ingredient safety and publishes its results in open, peer-reviewed literature. The FDA participates in the CIR in a non-voting capacity).

A study published in 2004 (Darbre, in the *Journal of Applied Toxicology*) detected parabens in breast tumours. The study also discussed this information in the context of the weak oestrogen-like properties of parabens and the influence of oestrogen on breast cancer. However, the study left several questions unanswered. For example, the study did not show that parabens cause cancer, or that they are harmful in any way, and the study did not look at possible paraben levels in normal tissue.

The FDA is aware that oestrogenic activity in the body is associated with certain forms of breast cancer. Although parabens can act similarly to oestrogen, they have been shown to have much less oestrogenic activity than the body’s naturally occurring oestrogen. For example, a 1998 study (Routledge *et al*, in *Toxicology and Applied Pharmacology*) found that the most potent paraben

tested in the study, butylparaben, showed from 10,000- to 100,000-fold less activity than naturally occurring oestradiol (a form of oestrogen). Further, parabens are used at very low levels in cosmetics. In a review of the oestrogenic activity of parabens (Golden *et al*, in *Critical Reviews in Toxicology*, 2005) the author concluded that based on maximum daily exposure estimates, it was implausible that parabens could increase the risk associated with exposure to oestrogenic chemicals.

The FDA believes that at the present time there is no reason for consumers to be concerned about the use of cosmetics containing parabens. However, the agency will continue to evaluate new data in this area. If the FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its legal options under the authority of the FD&C Act in protecting the health and welfare of consumers.

In conclusion on parabens, it is unbelievable that any company could make mileage and a unique sales proposition from saying that parabens are unsafe, when in reality the opposite is true. Clearly any company trying to make a strong case for not using parabens is uninformed and technically incompetent.

#### Contains no chemicals

Such claims are too ludicrous to warrant comment as everything is a chemical in one form or another.

#### Contains no preservatives

This is another way of saying that the product contains none of the preservatives listed in Annex V1 of the legislation, which in law would be viewed as illegal. However, there are some raw materials which, when added to a product, reduce the level of preservative required to protect the product and may even offer sufficient preservative action to allow a product to pass the BP or USP microbiological challenge test.

These materials may be perfumery ingredients as in the Dr Straetmans Dermofeel range, Naticide from Sinerga, or Neopein and Biopein from Bio-Botanica, etc. There is also a whole raft of

botanical extracts based on grapefruit seed extract, but be careful because on one website the following statement was found:

“Grapefruit extract is made by first converting grapefruit seeds and pulp into a very acidic liquid. This liquid is loaded with polyphenolic compounds, including quercetin, helperidin, campherol glycoside, neohelperidin, naringin, apigenin, rutinolide, poncirin, etc. The polyphenols themselves are unstable but are chemically converted into more stable substances that belong to a diverse class of products called quaternary ammonium compounds.

“Some quaternary compounds, for example benzethonium chloride and benzalkonium chloride, are used industrially as antimicrobials, but are toxic to animal life. The B vitamin choline is also a quaternary compound, but is non-toxic and even essential for maintaining healthy neurological function and fat metabolism.

“This material features the best of both worlds: the quaternary compounds derived from grapefruit exhibit broad-spectrum antimicrobial activity, while evidencing none of the toxic side-effects of chemically-derived quaternaries.”

By its own admission this material is a synthetic (albeit a natural source) derivative and could not be called “Citrus Paradisi (Grapefruit) Seed Extract” as shown in the CTFA Cosmetic Ingredient Dictionary. How many natural cosmetics use this material which, by admitted definition, is not a natural preservative? High levels of alcohol, glycols and sugars may also give a high level of self-preservation.

#### **Contains no petrochemicals**

The *Britannica Concise Encyclopaedia* defines petrochemical as “strictly, any of a large class of chemicals (as distinct from fuels) derived from petroleum and natural gas. The category has been broadened to include a much larger range of organic compounds and a few inorganic compounds including carbon black, sulphur, and ammonia. Some materials cannot be classified unequivocally because they have alternative sources (e.g. benzene from coal, ethanol from fermentation). Like crude oil and natural gas, most petrochemicals consist mainly of carbon and hydrogen and are called hydrocarbons. Petrochemicals used as raw materials (feedstocks) include ethylene, propylene, butadiene, benzene, toluene, xylene, and naphthalene.

The word “natural” in natural gas needs further investigation to understand the source for these petrochemicals: “Crude oil, natural gas and coal are fossil fuels and were formed from the fossilised remains of dead plants and animals that once lived millions of years ago. Oil and natural gas are the products of the deep burial and decomposition of dead plants and animals. Heat and pressure, in the absence of oxygen, transform the decomposed material into tiny pockets of gas and crude oil. The oil and gas then migrates through the pores in the rocks to eventually collect in reservoirs. Coal comes mainly from dead plants which have been buried and compacted beneath sediments. Most coal originated as peat in ancient swamps created many millions of years ago”. (Source: [www.moorlandschool.co.uk/earth/earthresources.htm](http://www.moorlandschool.co.uk/earth/earthresources.htm))

From this it is clear that petrochemicals are unequivocally natural. Maybe the marketeers who describe their products as “containing no petrochemicals” are thinking of specific materials, such as the low molecular weight mineral oils that were a concern in some food packaging as a potential source of carcinogenic materials. Perhaps they are thinking of the aniline hair dyes. But whatever they are thinking, they should avoid generalised and irrational statements about petrochemicals, a category that includes products such as the wonderfully protective, safely moisturising and effective skin barrier known as petrolatum or petroleum jelly, beloved by dermatologists for decades.

#### **Contains no animal derivatives**

While some may choose not to, man was designed to be a meat eater: his dentition is set up for tearing and chewing meat and the digestive system is tailored to the processing of that energy source. However, we no longer eat every part of the animal and the waste products that remain go to the pet food industry and to the soap makers. The fat produces tallow that can then be saponified into tallowate soap, an excellent way to use up much of the fatty waste. Other waste, particularly hooves and horns, can be used to extract the gelatin used in jellies and other food stuffs as a thickener. The skin and other tissue are also a valuable source of proteins, keratin, stearic acid and other useful cosmetic derivatives.

Now, however, there is a move against animal derivatives, despite their usefulness and functionality, and the demand for these slaughterhouse products has gone into decline. This previously valuable resource is now being

burnt or is destined for a landfill site. This is hardly the green, caring-for-the-environment promise made on the natural label. It is positively wasteful, contributing a massive and potentially toxic selection of waste gases if burnt, or some foul decomposition products if thrown into valuable landfill.

#### **Contains no synthetic fragrance**

This is a shame, because synthetic fragrances are unlikely to have the 26 allergens that need to be legally declared on any packaging. The ingredients in Table 2 that are highlighted in blue are found in natural essential oils. For example, lavender contains about 45% linalool, lemon contains around 73% limonene, lemongrass about 93% citral and cloves contain 92% eugenol. Clearly those that advocate the safety of natural fragrances over synthetic are neither chemists nor perfumers.

#### **Contains no sulphates**

Thankfully this claim is rarely seen because it is both ill-informed and meaningless. There are so many wonderful sulphates. For example, alum or potassium aluminium sulphate is astringent and very useful in some weeping skin conditions – it also makes a reasonable styptic. Glauber’s salts or sodium sulphate is a good choice for sitz baths. White vitriol, white copperas or zinc sulphate is used in treating stubborn skin conditions. Epsom salts or magnesium sulphate is another excellent additive to the bath for problematic skin conditions. The Roman spa ethic used *Sal polychrestum* or sulphurated potash which is potassium sulphate and *Sal enixum* which is potassium bisulphate. And Gypsum salts are calcium sulphate, as is plaster of Paris. Not many hazards to be seen within the list of sulphates. Perhaps the marketeer in this case meant Sodium Lauryl Sulphate (SLS).

#### **Contains no SLS**

The irony of this is that SLS is one of the most natural detergents produced from nature by man. It is chemically simple in structure and the process to make SLS is relatively unsophisticated, giving a detergent that is close to coconut fatty acids. Any mention that SLS is a carcinogen is without any fact or substance.

An article published in the *Journal of the American College of Toxicology*, Volume 2, Number 7, pp. 127- 181 (1983) states that Sodium Lauryl Sulphate and Ammonium Lauryl Sulphate appear to be safe in formulations designed for discontinuous, brief use

followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.

In July 2000, the CTFA (Cosmetic, Toiletry and Fragrance Association – [www.ctfa.org](http://www.ctfa.org)) issued the following: Response Statement: Internet-spread rumours about Sodium Lauryl Sulfate (SLS) and Sodium Laureth Sulfate (SLES) are false and unsubstantiated, in which it stated that:

“It has come to our attention that an e-mail is currently circulating on the Internet which falsely states that Sodium Lauryl Sulfate (SLS) and Sodium Laureth Sulfate (SLES), ingredients used primarily in some cosmetic ‘rinse off’ products, are unsafe. The story relayed via e-mail is an unsubstantiated story. It is typical of Internet rumors notorious for inaccurate and false information. “There is no evidence of harm from the use of either SLS or SLES as used in cosmetic products. Both ingredients were reviewed in 1983 by the Cosmetic Ingredient Review (CIR) Expert Panel and found to be safe. Complete reports on both ingredients are available from CIR.”

The Canadian Health Protection Branch (part of the Canadian government) has branded SLS e-mail stories as a hoax. On its website ([www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)) Health Canada goes on to say “Health Canada considers SLS safe for use in cosmetics. Therefore, you can continue to use cosmetics containing SLS without worry.” The American Cancer Society ([www.cancer.org](http://www.cancer.org)) also rejects the view that SLS is carcinogenic, and NICNAS (the National Industrial Chemicals Notification and Assessment Scheme) in Australia has prepared a useful summary of all the factual published data which can be found at [www.nicnas.gov.au](http://www.nicnas.gov.au)

In 1997 an OECD report concluded that: “The human health hazard assessment for SLS shows that at present the substance is of no concern for the general public (consumers) and for workers” and similarly a 1983 CIR report concluded: “SLS [and ALS] appear to be safe in [cosmetic] formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.”

Overall, there are no data in the OECD and CIR reports on SLS and their formulations to indicate SLS to be a skin sensitiser, genotoxic, carcinogenic, or a reproductive toxicant. The toxicity of SLS

appears to be restricted to acute toxicity and skin and eye irritation. Indeed, for chronic toxicity an oral study in the rat indicates that the primary health effect of SLS appears to be local irritation. However, these health effects are primarily based on the effects of SLS at high doses in studies in laboratory animals. The risk to humans from SLS will depend on the amount of exposure to the chemical. The amounts of SLS used in cosmetics, and hence the potential human exposure, is significantly smaller than that used in animal studies. Consequently, considering the human health effects associated with SLS together with data indicating potentially extensive use in both industrial and consumer areas, it appears that for consumers and workers, the human health hazards are low.

There can be no excuse for the claims made against SLS. The risk or irritation in a leave-on product is no worse than any other concentrated and powerful detergent. There would be no instance when SLS would be left on the skin, it is a detergent and in all cases would be rinsed off anyway. It is a fabulous foaming agent, with masses of bubbles and leaves hair squeaky clean.

#### **Contains no PEGS or ethoxylates**

Sadly, this is a case of more nonsense written by those who wish to create a marketing opportunity based on ignorance and/or the intention to deceive. The truth is that ethylene oxide is used to produce an ethoxylate by grafting an ethylene oxide unit onto a carbon chain backbone. The fully reacted ethylene oxide (which is a carcinogen in its raw state) is totally reacted and the resultant molecule is left milder as a result of this reaction. Thus sodium lauryl sulphate (SLS) when reacted with ethylene oxide becomes sodium lauryl ether sulfate (SLES) or sodium laureth sulphate; the two are not the same. The interesting result of this transformation is that the new SLES has about one eighth of the irritancy of the original SLS. Furthermore, if more ethoxylation is added to the SLES to achieve a higher than normal two mole ethoxylate, then the irritancy decreases still further. So much for the scare stories.

Often you will notice that cocamidopropyl betaine (CAB) has been added to an SLES formula. Blending CAB (25%) and SLES (75%) gives an irritancy value far less than if either of these materials were used alone – this is a synergistic effect.

In order to make an emulsion there is a need to stabilise the oil and water, which as everybody will know are not miscible. The way to keep these two

phases in a stable emulsion is to use an emulsifier and it is in these cases where the use of ethoxylated materials is most prevalent. The long chain carbon part of the molecule wants to dissolve in the oil phase, and the inclusion of an ethoxylated part gives a water loving end to the molecule. The emulsifier acts as a bond between the two and so helps to form a stable colloid.

There is another use for these ethoxylated materials and that is as a solubiliser for the perfume in an eau de toilette or aftershave. Alcohol may partially dissolve some of the oily perfume, but the addition of an ethoxylated material makes the product crystal clear and far more stable and resistant to the cold (when the product might otherwise go cloudy as the perfume comes out of solution as the temperature drops).

In conclusion for ethylene oxide, it is a carcinogen in its raw state, but not when it is reacted out to form an ethoxylated compound (any more than concentrated sulphuric acid is dangerous when reacted with a strong alkali to form a salt and water).

#### **Contains no dimethicone**

This was a recent discovery on a label and I was puzzled as to why this inert and wonderful material that is so lubricious on the skin should be a target for another marketing rejection. After much thinking I decided that it could only be because of the complications caused by very old prosthetic breast implants, which used silicon oil, that had burst or leaked. Hardly a problem in topical skin products; just another case of misinformation.

#### **Contains no pesticides**

I have not managed to find any product formulated with a pesticide and I hope that the marketer that came up with this suggestion was well rewarded for such an inane strap line.

#### **Organic Certification**

The Organic Certification scheme was designed for foods and it is perfectly understandable that a product would want to use an oil or material that had been produced under organic conditions so that the ingredient could be highlighted as coming from organic conditions. However, to certify a product as organic does not make quite so much sense. Water, for example, is not considered organic. This is surprising since it falls out of the heavens as a pure substance and is then purified by distillation or demineralisation to remove



anything it might have picked up on its journey to the factory tap. To get around this somebody had the clever, but very expensive idea of using a distilled floral water (the steam condensate from producing essential oil from an organic feedstock). Strangely, the Soil Association says that this does not count and only 30% of the floral water can be considered as organic. (Mystified? You are not alone!) The alternative is to use 1:1 Aloe vera gel, which is organic of course, but what would happen if we shipped the 10:1 organically certified concentrate and then replaced the 90% of water taken out to reduce shipping costs when it arrived at our factory? The truth is that nobody knows the answer yet.

The question of whether organic is any different to non-organic remains another mystery. We have examined organically grown extracts versus non-organic, and we have also looked at organic fixed oils versus non-organic. The overall opinion is that in the most part the organic oils are of inferior quality as the colour is often considerably worse, the rancidity is more developed and therefore the odour is poorer. A molecule does not know it is organic and so *gamma* linolenic acid found in organic Evening Primrose Oil is identical to that found in regular Evening



Evening Primrose (*Oenothera biennis*).

Primrose Oil (*Oenothera biennis*). To use organic material is a very good way of paying four times the price per kilogram for an inferior product.

#### **Fair Traded**

A wonderful idea that helps the poorer countries to make a living, but do make sure that the scheme has been vetted, audited and is genuine, because there are those that would exploit the idea, charge the higher prices but not reward the workers as promised.

#### **Conclusion**

It would be refreshing to see a return to the truth confirmed by science, rather than the marketing claims that are being

generated and perpetrated by non-scientific lay people. The cosmetic and toiletry industry is well regulated and the laws are fierce and robust, supported by independent safety assessors, toxicologists, the SCCP (Scientific Committee for Consumer Products), CIR (Cosmetic Ingredient Review), IFRA (International Fragrance Research Association), and independent researchers. Basing a range of products on farcical and untruthful "facts" is a trend that should be stopped immediately by prosecuting those companies for unfair trading and misleading the consumer.

The industry is in danger of going out of control and there needs to be a stand taken against the ridiculous statements made on some of the products being sold in our industry. Some claims are so ludicrous that it is only a matter of time before the consumers realise that some of those in our industry are not only dishonest but also guilty of using meaningless statements. If we want to remain respected and to be taken seriously, then it is the duty of each of us to stamp out this type of product. Tough words perhaps, but we either regulate ourselves or face being legislated out of any degree of freedom and damned to a life of even more bureaucracy. **PC**